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Patent Application
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Alejandro Dee, et al.

Date:

Date Filed: February 20, 1996

Docket No.: BABSBRO-7

App. No.: 08/602,498

Art Unit: 1617

For: FATTY ACID ANTIMICROBIAL

Examiner: M. MOEZE

DECLARATION OF ALEJANDRO DEE

I, Alejandro Dee, hereby declare and state as follows:

1. I am employed by Westfalia-Surge, LLC, formerly known as Babson Bros. ("Babson") and am a named inventor in the above-noted application.

2. In early 1993, Babson received a commercially available product sample from Dr. Michael Gardner, which he claimed had conditioning properties and also thought could be the basis for a new teat dip. Dr. Gardner did not know the individual components of the sample.

3. Upon receipt of the sample, we analyzed it to determine its components. Analysis revealed that the sample contained propylene glycol, propyl gallate, butyl hydroxy anisole ("BHA"), and nitrofurazone.

4. Babson scientists then attempted to devise a teat dip formulation involving some of these components. Although nitrofurazone was germicidal, it could not be used in a teat dip because

nitrofurazone is a carcinogen. Initial formulations, which contained propylene glycol, propyl gallate, and BHA, were tested by Charles Gradle in Babson's laboratory, but were found to be less effective in those tests than currently available commercial teat dips.

5. Mr. Gradle and I then conceived the idea of adding a fatty acid or mixture of fatty acids as a germicide to the formulation, which by now had been given the experimental designation DX-206.

6. The formulation was then developed by Charles Gradle and me in Babson's laboratory. During this time, the BHA was removed from the DX-206 formulation, because it was considered a carcinogen in California. By December 6-7, 1994, the BHA had been removed from the DX-206 formulation. At that time, DX-206 contained 1.03% of a fatty acid mixture, 92.8% propylene glycol, 0.1% methyl paraben, 0.05% FD&C Yellow No. 6, and 6% water.

7. Although this product performed satisfactorily in laboratory tests, I did not know how it would perform in actual use on dairy animals. As a result, a quantity of DX-206 was provided to Dr. Gardner on January 31, 1995 for field testing by his clients in their herds.

8. At the time it was sent to Dr. Gardner, the DX-206 formulation was not a commercial product. It had undergone no field testing, and had not been subjected to protocol testing using control animals to determine its efficacy in a more quantitative way. In my opinion, if the DX-206 formulation sold to Dr. Gardner had not performed satisfactorily in the herds of Dr. Gardner's clients, that formulation would not have been commercialized. In fact, the final commercial product based on DX-206, Dermasept, differed from the DX-206 formulation tested by Dr. Gardner's clients in among other things, the amount of water in the formulation. This change was made due to reports of unsatisfactory performance of DX-206 by some of Dr. Gardner's clients.

9. During the field testing process, Dr. Gardner kept Babson informed on a regular basis as to the results of the tests, and any problems that arose with respect to DX-206. For example, Dr. Gardner returned a sample to Babson for analysis after Dr. Gardner's client had reported that DX-206 was irritating to the skin of his animals.

10. The DX-206 formulation was changed based on the results of Dr. Gardner's field testing. For example, in October 1995, based on complaints from some of Dr. Gardner's clients that DX-206 did not work well in teat dip sprayers, more water was added to the formulation to make the product easier to spray. Wintergreen was also added at this time to improve the odor of the product.

11. DX-206 was not approved for sale by Babson until May 1996 under the name Dermasept™.

12. In my opinion, the early sales by Dr. Gardner DX-206 to his herd health clients were for testing purposes in the early development period of the product. Until I began to see positive results from the use of DX-206 in actual herds by his clients, I did not know whether DX-206 would have satisfactory efficacy against mastitis in harsh, real world conditions, or whether it would have the teat conditioning properties I hoped it would.

I do hereby certify that the foregoing is true and correct under penalties of perjury under the laws of the United States of America.

Date: 9 / 16 / 99

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